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EXAMINER				
KISHORE, GOLLAMUDI S				
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HANS E. J. HOFLAND

Appeal 2009-003409
Application 10/713,546
Technology Center 1600

Decided: January 25, 2010

Before DONALD E. ADAMS, DEMETRA J. MILLS, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

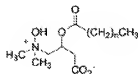
This appeal under 35 U.S.C. § 134 involves claims 8-11, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method for treating a peripheral arterial disease in a mammal. Claim 8 is illustrative:

8. A method for treating a peripheral arterial disease in a mammal, said method comprising:

administering a therapeutically effective amount of a liposomal formulation of a L-carnitine derivative, wherein said L-carnitine derivative is an alkyl-L-carnitine of formula



wherein n is an integer selected from the group consisting of 0, 4, 6, 8, 10, 12, 14 and 16, thereby treating a peripheral arterial disease in said mammal.

The Examiner relies on the following evidences:

Brevetti	US 4,968,719	Nov. 6, 1990
Cavazza	US 5,747,536	May 5, 1998
Foldvari	US 5,993,851	Nov. 30, 1999
Keller	US 6,726,924 B2	Apr. 27, 2004

The rejections presented by the Examiner follow:

1. Claims 8-11 stand rejected under 35 U.S.C § 103(a) as unpatentable over Cavazza in combination with Keller and/or Foldvari.
2. Claims 8-11 stand rejected under 35 U.S.C § 103(a) as unpatentable over Brevetti, Cavazza in combination with Keller and/or Foldvari.

We affirm.

ISSUE

Has Appellant established error in the Examiner's prima facie case of obviousness?

FINDINGS OF FACT

- FF 1. “Cavazza teaches the effectiveness of L-carnitine and its esters in the treatment of peripheral vascular diseases” (Ans. 3).
- FF 2. “The derivatives taught by Cavazza are acetyl L-carnitine and propionyl L-carnitine (abstract, columns 3-5 and claims” (*id.*).
- FF 3. Cavazza fails to teach “the use of liposomes as the delivery vehicles for carnitines” (*id.*).
- FF 4. “Brevetti teaches L-carnitine’s effectiveness for the treatment of peripheral vascular diseases (abstract, Examples and claims)” (Ans. 4).
- FF 5. Brevetti fails to teach “the use of liposomes as the delivery vehicles for Carnitine and the use of [the] claimed derivatives of carnitine” (*id.*).
- FF 6. Keller teaches “that liposomes are sustained release delivery vehicles for a variety of active agents including L-carnitine” and that “liposomes increase the bioavailability of active agents when administered (col. 2, lines 13-65)” (Ans. 3 and 4).
- FF 7. Foldvari teaches “liposomal formulations containing various biologically active agents for topical delivery”; “that liposome encapsulation advantageously alters the pharmacokinetic fate of the drug after topical application”; and “that liposomes (containing active agent, PGE1) can be used to treat diseases including peripheral vascular disease (col. 27, lines 41-47)” (Ans. 3 and 4-5).

PRINCIPLES OF LAW

“[T]he [E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). On appeal to this

Board, Appellant must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential); *Ex parte Fu*, 89 USPQ2d 1115, 1118 and 1123 (BPAI 2008) (precedential).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”) In sum, the “suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006).

During *ex parte* prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. *See In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

ANALYSIS

The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 8 is representative.

Based on the foregoing factual findings (FF 1-7) the Examiner concludes that it would have been *prima facie* obvious to use the L-carnitine derivative taught by Cavazza, or the combination of Brevetti and Cavazza, in

the liposomal formulation taught Keller to treat peripheral vascular disease (*see* Ans. 4 and 5).

Appellant contends that Cavazza fails to “suggest using alkyl-L-carnitines *alone* as the active agent in a pharmaceutical composition” and “actually *teaches away* from the use of a pharmaceutical composition comprising alkyl-L-carnitine alone as the active agent for the treatment of peripheral arterial disease as presently claimed” (App. Br. 6-7). We are not persuaded.

The method of Appellant’s claim 8 comprises, *inter alia*, the administration of a therapeutically effective amount of a L-carnitine derivative. Accordingly, the method of Appellant’s claim 8 *does not* exclude the presence of additional active ingredients in its liposomal formulation (*see* Ans. 7 (“instant claim language does not exclude other components taught by Cavazza”)).

Similarly, we are not persuaded by Appellant’s contention that while Keller teaches liposomal formulations comprising L-carnitine, Keller fails to teach or use L-carnitine derivatives, within the scope of Appellant’s claim 8, for treating peripheral arterial disease (App. Br. 8). Appellant does not dispute and therefore concedes that Cavazza teaches a method of administering a therapeutically effective amount of an alkyl-L-carnitine derivative, within the scope of Appellant’s claim 8, for the treatment of peripheral arterial disease. Appellant fails to provide a persuasive argument or evidence to support a conclusion that it would not have been *prima facie* obvious to a person of ordinary skill in this art to use Cavazza’s L-carnitine derivative in Keller’s liposomal formulation for the treatment of peripheral arterial disease as required by Appellant’s claim 8.

Since the combination of Cavazza and Keller supports the Examiner's prima facie case of obviousness, we do not address Foldvari, which the Examiner relied upon in the alternative.

Having found no deficiency in the combination of Cavazza and Keller we are not persuaded by Appellant's contention "that Brevetti does not supplement the deficiencies" in this combination (App. Br. 9). Further since Appellant does not dispute and therefore concedes that Cavazza teaches an alkyl-L-carnitine that is within the scope of Appellant's claim 8 we are not persuaded by Appellant's contention that Brevetti fails to teach "the use of certain alkyl-L-carnitine derivatives as *the* active agent in treating peripheral arterial diseases" (App. Br. 9).

CONCLUSIONS OF LAW

Appellant failed to establish error in the Examiner's prima facie case of obviousness.

The rejection of claim 8 under 35 U.S.C § 103(a) as unpatentable over Cavazza in combination with Keller and/or Foldvari is affirmed. Claims 9-11 fall together with claim 8.

The rejection of claim 8 under 35 U.S.C § 103(a) as unpatentable over Brevetti, Cavazza in combination with Keller and/or Foldvari. Claims 9-11 fall together with claim 8.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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